PREMARKET NOTIFICATION [510(K)] SUMMARY

NOV 15 2012

Date Prepared:	July 10, 2012
Submitter:	St. Jude Medical, CRMD
Address:	15900 Valley View Court Sylmar, CA 9134
Phone:	818 493 3134
Fax:	818 493 3615
Contact Person:	Plessy Paul
Trade Name/Proprietary Name:	SJM Confirm® Implantable Cardiac Monitor
Common Name:	Implantable Cardiac Monitor Model Numbers: DM2100
Classification:	Class II, 21 CFR 870.2800
Legally marketed device to which your firm is claiming equivalence:	SJM Confirm® Implantable Cardiac Monitor System K081365

Device Description:

The SJM Confirm® Implantable Cardiac Monitor is a minimally invasive, implantable diagnostic monitoring device with subcutaneous electrodes that are used for sensing and a looping memory for storage of electrograms (EGM). The device is comprised of three main components: the implantable cardiac monitor (Model DM2100) and the external patient activator (Model DM2100A). The third component is the programmer the physician uses to communicate to the cardiac monitor and associated programmer software. The programmer is the legally marketed SJM Merlin PCS programmer Model 3650 (with Software Model 3330).

The indication for use is as follows:

The SJM Confirm® Implantable Cardiac Monitor is indicated for monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, shortness of breath, and patients who are at risk for other cardiac arrhythmias.

Technological Characteristics of the Device Compared to the Predicate Device:

The SJM Confirm® ICM with the alternate collector cell battery has the same fundamental technological characteristics as the currently marketed SJM Confirm® ICM model DM2100, including same intended use, technology, design, material, chemical composition and energy source. The new implantable grade, collector design, Li-Thionyl Chloride Battery (LTC-3PN-S35) will be used as an alternate battery to our existing spike design LTC-3PN-S33. Both

collector design and spike design are manufactured by EaglePicher. No modifications are being made to the external patient activator component or the associated programmer software.

Summary of Testing:

In order to ensure that the SJM Confirm® ICM model DM2100, with alternate collector cell battery, meets the product and system specification, verification tests were performed. Device testing (documented in 60041954, **Attachment 3)** and component level testing (documented in QTR40008803, **Attachment 4**), confirms that alternate collector cell battery has no effects on the device performance.

Biocompatibility:

There is no change to the blood/tissue contact materials of the SJM Confirm® ICM device with alternate collector cell battery as compared to legally marketed St. Jude Medical Confirm® ICM Model DM2100 (K081365). Therefore, no biocompatibility testing was conducted.

Sterilization:

The SJM Confirm® ICM with alternate collector cell battery is sterilized using the same validated 100% Ethylene Oxide (EtO) sterilization process as legally marketed St. Jude Medical Confirm device, DM2100 (K081365).

Conclusion:

St. Jude Medical considers the SJM Confirm® ICM model DM2100, with alternate collector cell battery to be substantially equivalent to the legally marketed predicate and referenced device through the data and information presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 15 2012

St. Jude Medical, CRMD
c/o Ms. Plessy Paul
Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, CA 91324

Re: K122090
Trade/Device Names: SJM Confirm® Implantable Cardiac Monitor, Model DM2100
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (Two)
Product Code: MXC, DXH and DSH
Dated: November 1, 2012
Received: November 5, 2012

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

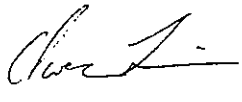
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122090

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name: SJM Confirm® ICM Model DM2100

Indications for Use:

The SJM Confirm® Implantable Cardiac Monitor is indicated for monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, shortness of breath, and patients who are at risk for other cardiac arrhythmias.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122090